



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2015-0717; FRL-9970-03]

Phenylethyl acetate; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of phenylethyl acetate (CAS Reg. No. 103-45-7) when used as an inert ingredient (solvent) at a maximum of 0.015% in pesticide formulations applied to growing crops and raw agricultural commodities after harvest. Technology Science Group Inc., on behalf of Janeil Biosurfactant Company, submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance.

DATES: This regulation is effective [*insert date of publication in the Federal Register*]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with

the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2015-0717, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: RDfRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American

Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them.

Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl. To access the OCSPP test guidelines referenced in this document electronically, please go to <http://www.epa.gov/ocspp> and select "Test Methods and Guidelines."

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2015-0717 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of*

*publication in the **Federal Register***]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2015-0717, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Petition for Exemption

In the **Federal Register** of November 23, 2015 (80 FR 72941) (FRL-9936-73), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN-10888) by Technology Sciences Group Inc., on behalf of Jeneil Biosurfactant Company, 400 N. Dekora Woods Blvd., Saukville, WI 53080. The petition requested that 40 CFR 180.910 be amended by establishing an exemption from the requirement of a tolerance for residues of phenylethyl acetate (CAS Reg. No. 103-45-7) when used as an inert ingredient (solvent) in pesticide formulations applied to growing crops and raw agricultural commodities after harvest at a maximum concentration not to exceed 0.015% by weight of the pesticide formulation. That document referenced a summary of the petition prepared by Technology Sciences Group Inc., the petitioner, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term “inert” is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate

exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for phenylethyl acetate including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with phenylethyl acetate follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by phenylethyl acetate as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit.

Phenylethyl acetate exhibits relatively low acute toxicity via the oral and dermal routes of exposure. Phenylethyl acetate has been reported to be moderately to severely irritating to the eyes of rabbits, but only mildly irritating to their skin and not dermally sensitizing to guinea pigs.

The toxicity database for phenylethyl acetate includes only one repeat dose toxicity study. In that study, a subchronic oral toxicity study via gavage, male rats received 73 mg/kg/day of phenylethyl acetate. There were no adverse effects seen at that dose, which was the only dose tested.

Studies of metabolism following oral ingestion suggests, phenylethyl acetate is rapidly absorbed, metabolized and excreted in the urine. Phenylethyl alcohol, phenylacetic acid and acetic acid are the primary metabolites. Phenylethyl alcohol is successively oxidized to phenylacetaldehyde and phenylacetic acid *in vivo*. Phenylacetaldehyde is oxidized by inducible aldehyde dehydrogenases and cytosolic isoenzymes to phenylacetic acid. Phenylacetic acid undergoes species-specific conjugation with a variety of amino acids, amines, or glucuronic acid followed by excretion almost exclusively in the urine. All of these metabolites are all naturally occurring compounds and are normal constituents of the human body. No toxicological endpoint of concern has been identified for any of these phenylethyl acetate metabolites.

The Research Institute for Fragrance Materials, Inc. (RIFM) reported results of three Ames assays performed on phenylethyl acetate. Results of all three showed no significant increase in reverse mutations in *Salmonella typhimurium* strains TA98, TA100, TA1535, or TA1537 in the presence or absence of metabolic activation at concentrations up to 5000 µg/plate phenylethyl acetate.

No carcinogenicity studies were available in the database for phenylethyl acetate; however, a DEREK model showed no structural alerts for carcinogenicity, and the genotoxicity studies were negative.

No immunotoxicity studies were available in the database for phenylethyl acetate. However, phenylethyl acetate is readily metabolized to phenylethyl alcohol, phenylacetic acid and acetic acid which are all naturally occurring compounds and are normal constituents of the human body. No toxicological endpoint of concern has been identified for any of these phenylethyl acetate metabolites.

No neurotoxicity studies were available in the database for phenylethyl acetate. However, cholinesterase activity was not affected nor was there systemic toxicity in a study in rats treated via gavage with 73 mg/kg/day phenylethyl acetate for 140 days. Additionally, the chronic reference dose (cRfD) is based on this study and any potential neurotoxic effects will be protected.

B. Toxicological Points of Departure/Levels of Concern

Phenylethyl acetate is readily metabolized to phenylethyl alcohol, phenylacetic acid and acetic acid which are all naturally occurring compounds and are normal constituents of the human body. No toxicological endpoint of concern has been identified for any of these phenylethyl acetate metabolites. For purposes of conducting a risk assessment in support of this action, a highly conservative toxicological point of departure of 73 mg/kg/day for all nonacute exposure durations and routes of exposure was selected for phenylethyl acetate based on the NOAEL from the subchronic rat oral toxicity study. A chronic population adjusted dose (cPAD) of 0.73 mg/kg/day was derived based on the use of the POD and 10X inter- and intraspecies uncertainty factors and an FQPA Safety Factor of 1X.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to phenylethyl acetate, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from phenylethyl acetate in food as follows:

i. *Acute Exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide chemical, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. No such effects were identified in the toxicological studies for phenylethyl acetate; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* The chronic dietary exposure assessment for this inert ingredient utilizes the Dietary Exposure Evaluation Model Food Commodity Intake Database (DEEM-FCID), Version 3.16, EPA, which includes food consumption information from the U.S. Department of Agriculture's National Health and Nutrition Examination Survey, "What We Eat In America", (NHANES/WWEIA). This dietary survey was conducted from 2003 to 2008. In the absence of actual residue data, the inert ingredient evaluation is based on a highly conservative model which assumes that the residue level of the inert ingredient would be no higher than the highest established tolerance for an active ingredient on a given commodity. Implicit in this assumption is that there would be similar rates of degradation between the active and inert ingredient (if any) and that the concentration of inert ingredient in the scenarios leading to these highest of tolerances would be no higher than the concentration of the active ingredient. The model assumes 100 percent crop treated (PCT) for all crops and that every food eaten by a person each day has tolerance-level residues. A complete description of the general

approach taken to assess inert ingredient risks in the absence of residue data is contained in the memorandum entitled “Alkyl Amines Polyalkoxylates (Cluster 4): Acute and Chronic Aggregate (Food and Drinking Water) Dietary Exposure and Risk Assessments for the Inerts.” (D361707, S. Piper, 2/25/09) and can be found at <http://www.regulations.gov> in docket ID number EPA–HQ–OPP–2008–0738. In the case of phenylethyl acetate, an adjustment to the dietary exposure analysis was made to account for the use at a maximum concentration of 0.015% in pesticide formulations. As part of the aggregate exposure assessment, dietary exposures to phenylethyl acetate resulting from its use as a food flavoring agent are also included in the assessment.

2. *Dietary exposure from drinking water.* For the purpose of the screening level dietary risk assessment to support this request for an exemption from the requirement of a tolerance for phenylethyl acetate, a conservative drinking water concentration value of 100 ppb based on screening level modeling was used to assess the contribution to drinking water for the chronic dietary risk assessments for parent compound. These values were directly entered into the dietary exposure model.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables).

Phenylethyl acetate may be used as inert ingredient in pesticide products that are registered for specific uses that may result in indoor or outdoor residential exposures. A screening-level residential exposure and risk assessment was completed utilizing conservative residential exposure assumptions. The Agency assessed short- and

intermediate-term dermal and inhalation exposures for residential handlers that would result from low pressure handwand, hose end sprayer and trigger sprayer for outdoor scenarios of each pesticide type (herbicide, insecticide and fungicide) and mopping, wiping and aerosol sprays for indoor scenarios. The Agency assessed post-application short-term dermal exposure for children and adults as well as short-term hand-to-mouth exposure for children from contact with treated lawns.

Residential exposures to phenylethyl acetate may also occur as a result of its use as a fragrance component. Estimates of these exposures are included in the aggregate exposure assessment of phenylethyl acetate.

4. *Cumulative effects from substances with a common mechanism of toxicity.*

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

EPA has not found phenylethyl acetate to share a common mechanism of toxicity with any other substances, and phenylethyl acetate does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that phenylethyl acetate does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

D. Safety Factor for Infants and Children

Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

As part of its assessment, EPA evaluated the available toxicity, metabolism and exposure data on phenylethyl acetate and considered its validity, completeness, and reliability, as well as the relationship of this information to human risk. No hazard was identified based on the available studies. EPA has identified no residual uncertainty with regard to prenatal and postnatal toxicity or exposure to phenylethyl acetate; therefore, EPA concludes that no additional margin of exposure (safety) is necessary for the protection of infants and children.

E. Aggregate Risks and Determination of Safety

Taking into consideration all available information on phenylethyl acetate, EPA has determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to phenylethyl acetate under reasonable foreseeable circumstances. Therefore, the establishment of an exemption from tolerance under 40 CFR 180.910 for residues of phenylethyl acetate when used as an inert

ingredient in pesticide formulations applied on growing crops and raw agricultural commodities after harvest at a maximum of 0.015% in the pesticide formulation, is safe under FFDCA section 408.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, phenylethyl acetate is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to phenylethyl acetate from food and water will utilize <0.01% of the cPAD for children 1-2 years old, the population group receiving the greatest exposure.

3. *Short-, intermediate- and long-term risk.* Short-, intermediate- and long-term aggregate exposure takes into account short-, intermediate- and long-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Phenylethyl acetate is currently used as an inert ingredient in pesticide products that are registered for uses that could result in short- and intermediate-term residential exposure, and there are other, non-pesticidal residential uses of phenylethyl acetate that could result in long-term residential exposures; the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-, intermediate- and long-term term residential exposures to phenylethyl acetate.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined respective short-, intermediate- and long-term term food, water, and residential exposures result in aggregate margin of exposures (MOE) of 560 for adults and 19,000 for children. Because EPA's level of concern for phenylethyl acetate is a MOE of 100 or below, these MOEs are not of concern.

4. *Aggregate cancer risk for U.S. population.* Based on the discussion in Unit IV.A., phenylethyl acetate is not expected to pose a cancer risk.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to phenylethyl acetate residues.

V. Analytical Enforcement Methodology

Although EPA is establishing a limitation on the amount of phenylethyl acetate that may be used in pesticide formulations, an analytical enforcement methodology is not necessary for this exemption. The limitation will be enforced through the pesticide registration process under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 et seq. EPA will not register any pesticide for sale or distribution for use on growing crops with concentrations of phenylethyl acetate exceeding 0.015% by weight of the formulation.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.910 for phenylethyl acetate (CAS Reg. No. 103-45-7) when used as an inert

ingredient (solvent) in pesticide formulations applied to growing crops and raw agricultural commodities after harvest at a maximum of 0.015% in the pesticide formulation.

VII. Statutory and Executive Order Reviews

This action establishes an exemption from the requirement of a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VIII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to

publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: December 12, 2017.

Michael Goodis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In §180.910, add alphabetically the inert ingredient to the table to read as follows:

§ 180.910 Inert ingredients used pre- and post-harvest; exemption from the requirement of a tolerance.

* * * * *

Inert ingredients	Limits	Uses
***	*	***
Phenylethyl acetate (CAS Reg. No. 103-45-7)	Not to exceed 0.015% in pesticide formulation.	Solvent
***	*	***

[FR Doc. 2017-28317 Filed: 12/29/2017 8:45 am; Publication Date: 1/2/2018]